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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,757	09/08/2000	Anna Maria Helena Boots	0/96198US	2735

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EXAMINER
NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
1644	6

DATE MAILED: 04/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/657,757	Boots et al.
Examiner	**Art Unit**
Patrick J. Nolan	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 14, 2002*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2-5, 7, and 10-17* is/are pending in the application.

4a) Of the above, claim(s) *4, 5, 10, 12, and 15* is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2, 3, 7, 11, 13, 14, 16, and 17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Part III DETAILED ACTION

1. Claims 2-5, 7, 10-17. are pending.

2. Applicant's election with traverse of Groups I-XXV, in Paper No. 5 is acknowledged. Upon a further conversation with William Ramey, it was communicated that Groups 1-XXV were 25 separate and distinct groups. Mr. Ramey provisionally elected Group I, peptide SEQ ID NO. 1. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-5, 10, 12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Furthermore, claim 15 is also being withdrawn to a non-elected invention since as currently recited it is not identical in scope with the allowed claim in U.S. Patent 6,184,204, since consisting of and containing language are not identical in scope.

Claims 2, 3, 7, 11, 13-14 and 16-17 are presently being examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2, 3, 7 and 13-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hakala et al. (W).

Hakala et al., teaches the sequence of the full length HC gp-39 protein in a pharmaceutical composition with a pharmaceutically acceptable carrier (see page 25804 and 25807, in particular). Claims 2, 3, 7 and 13-14 are read as open ended because of the terms having in claim 2 and containing in line 2 of claims 13 and 14. If Applicant wishes to exclude their peptides reading on the full length protein from which they were derived, the only acceptable claim language is "consisting of".

The prior art teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 11 is rejected under 35 U.S.C. § 103 as being unpatentable over Hakala et al.

Hakala et al., has been discussed supra.

The claimed invention differs from the prior art teaching(s) only by the recitation of a kit with said protein.

One skilled in the art would have recognized the usefulness of supplying a protein kit for use in diagnostic assays. Test kits are compounds packaged for the convenience of the practitioner and are conventionally made to reproducibly obtain results under test conditions and it is conventional to assemble all necessary reagents, including antibodies, buffers and standards for the convenience of the practitioner and commercial expediency. Furthermore, the preamble reciting "A kit for ..." does not convey any patentable weight to the actual components of the kit itself.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to assay for the presence of gp-39 as taught by the Hakala et al., and package the assay as a kit with the expectation that kits allow for ease and commercial reproducibility of known assays.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's specification has no working examples demonstrating the enablement of the claimed invention.

In endogenous peptide therapy, the goal of peptide immunotherapy of T-cell-mediated autoimmunity (rheumatoid arthritis is a T cell mediated autoimmune disease) is to induce anergy in self reactive T cells. However Wraith et al., (U, Cell 59: 247-255, 1989) teach the "Inhibition of the response restricted by one class II molecule may lead only to the escape to an autoimmune response to a separate epitope restricted by a different class II molecule." (page 253 column 1, in particular).

Furthermore, Tisch et al., (V, P.N.A.S. 91:437-438) teach that treating an ongoing T-cell-mediated autoimmunity by administering an antigen peptide may have an immunizing effect and exacerbate the disease condition (page 437, column 3, in particular). Since applicant has not provided any working examples of the efficacy of the endogenous peptides in treating already established rheumatoid arthritis, it would require and undue amount of experimentation to one of skill in the art to practice the claimed invention and this is not sanctioned by the statute.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
April 8, 2002